



PACKAGING
(ESSENTIAL REQUIREMENTS)
REGULATIONS

Government Guidance Notes

Packaging (Essential Requirements) Regulations 2003

Government Guidance Notes

(S.I. 2003 No. 1941 as amended by S.I. 2004 No. 1188 and S.I. 2006 No. 1492)

January 2007

This Guide is intended to assist those involved in the placing of packaged goods on the market and the enforcement authorities. It aims to explain the Regulations as interpreted by the DTI.

The Regulations themselves should always be read and understood, as they constitute the law, in contrast with the Guide, which is informative but has no legal authority.

You should refer to the Regulations themselves for a full statement of the legal requirements and in the case of any doubt take your own independent legal advice. The Regulations may be changed from time to time, so users should take care to keep themselves informed. In this regard, information may be obtained from the DTI's Recycling Policy Unit. Details of contacts for further information are given on pages **15, 16 and 17.**

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The Regulations – In brief

The Packaging (Essential Requirements) Regulations 2003 (SI 2003 No 1941) (“the 2003 Regulations”) are amended by the Packaging (Essential Requirements) (Amendment) Regulations 2004 (SI 2004 No 1188) (“the 2004 Regulations”) and the Packaging (Essential Requirements) (Amendment) Regulations 2006 (SI 2006 No 1492) (“the 2006 Regulations”).

The Regulations implement provisions of the European Parliament and Council Directive on Packaging and Packaging Waste (94/62/EC) ("the Directive") relating to the essential requirements to be satisfied by packaging in order to circulate freely on the single market. Packaging manufactured before 31 December 1994 and lawfully placed on the market before 31 December 1999 is excluded from these requirements.

The 2003 Regulations include the addition of derogations from the heavy metals limits in respect of certain glass packaging and plastic pallets and crates as set out in Commission Decisions 1999/177/EC and 2001/171/EC and the introduction of a set timeframe for producing proof of compliance of 28 days. The 2003 Regulations came into effect on 25 August 2003, revoking and replacing the original Packaging (Essential Requirements) Regulations 1998 (SI 2998/1165).

The European definition of "packaging" was amended by Directive 2004/12/EC, published on 18 February 2004. This amendment introduces an indicative list containing examples of what does and does not constitute "packaging", in order to provide clarity for the purposes of producers and other interested parties. The 2004 Regulations include this amendment. For further details, please see page 7.

The 2003 derogation for glass packaging in relation to the heavy metal concentration levels was due to expire on 30 June 2006. The provisions of the derogation were extended indefinitely and transposed into UK law by the 2006 Regulations which came into force on 1 July 2006.

These Regulations do not affect the application of existing quality requirements for packaging, including those regarding safety, the protection of health and hygiene of the packed products, existing transport requirements or provisions on hazardous waste. In other words, existing legislation on these matters must also be complied with.

Requirements

The main requirement is that no person who is responsible for packing or filling products into packaging or importing packed or filled packaging into the United Kingdom may place that packaging on the market unless that packaging fulfils the Essential Requirements and is within the heavy metal concentration limits.

Essential Requirements

The Essential Requirements are, in summary:

- Packaging volume and weight must be the minimum amount to maintain necessary levels of safety, hygiene and acceptance for the packed product and for the consumer
- Packaging must be manufactured so as to permit reuse or recovery in accordance with specific requirements
- Noxious or hazardous substances in packaging must be minimised in emissions, ash or leachate from incineration or landfill

Heavy Metal Limits

Aggregate heavy metal limits apply to cadmium, mercury, lead and hexavalent chromium in packaging or packaging components subject to some exceptions. The total by weight of such metals should not exceed:

- 600 ppm on or after 30 June 1998
- 250 ppm on or after 30 June 1999
- 100 ppm on or after 30 June 2001

Enforcement

Trading Standards Officers may assess the compliance of any packaging by requesting technical documentation on both the essential requirements and the heavy metal limits. This documentation must be produced within **28 days** of the request being made.

Packaging and the Single Market

Achieving the free movement of goods, in this case packaging, lies at the heart of the drive to create the single European market. In May 1985, European Community Ministers agreed on a 'New Approach to Technical Harmonisation and Standards' to fulfil this objective.

'New Approach' EC Directives set out the essential requirements, usually written in general terms, which must be met before products may be placed on the market in the United Kingdom or anywhere else in the European Community. Mandated European harmonised standards in respect of a product provide detailed characteristics and tests which meet the essential requirements.

Use of the standards is voluntary and manufacturers are free to choose alternative means in order to demonstrate compliance. However, demonstrating conformity with the harmonised standards provides a "presumption of compliance" with the essential requirements of the Packaging Directive and Member States are obliged to grant market access to packaging meeting the standards.

A series of seven standards in relation to packaging were published by the European Committee for Standardization (CEN) and have been in use in the UK for demonstrating compliance with the essential requirements (see Annex A). The table on Page 19 lists the current standard and references to the revised texts.

Packaging (Essential Requirements) Regulations

Scope

The Definition of Packaging

These Regulations apply to all packaging placed on the market in the United Kingdom as packed or filled packaging. Packaging is defined as all products made of any material of any nature used for the containment, protection, handling, delivery and presentation of goods, from raw materials to processed goods, from the producer to the user or the consumer, but only where the products are sales or primary packaging; grouped or secondary packaging or transport or tertiary packaging as defined. The full definition is in the Regulations and is clarified by three additional criteria. These are:

- (i) Items shall be considered to be packaging if they fulfil the abovementioned definition without prejudice to other functions which the packaging might also perform. However, where an item is an integral part of a product and it is necessary to contain, support or preserve that product throughout its lifetime and all elements are intended to be used, consumed or disposed of together, the item will not constitute packaging for the purposes of the Regulations.
- (ii) Items designed and intended to be filled at the point of sale and "disposable" items sold, filled or designed and intended to be filled at the point of sale shall be considered to be packaging only if they fulfil a packaging function.
- (iii) Packaging components and ancillary elements integrated into packaging shall be considered to be part of the packaging into which they are integrated. Ancillary elements hung directly on, or attached to, a product and which perform a packaging function shall be considered to be packaging but will not be considered packaging if they are an integral part of the product and all elements are intended to be consumed or disposed of together.

An indicative list of what is and is not considered packaging under each of these three criteria are set out in Annex C.

Further guidance as to the interpretation of packaging has been published by the Environment Agencies (see contact points). However, anything recognised as packaging and in use as packaging would in general be likely to be covered by these Regulations.

Placing on the Market

"Placing on the market" is not defined in the Regulations, but is generally taken to refer to the first occasion on which the assembled (i.e. packed/filled) packaging is transferred with the intention of sale or distribution on the market including the EEA¹ market.

¹ European Economic Area. Norway, Iceland and Liechtenstein participate in the Internal Market whilst not assuming full responsibilities of EU membership.

Whether the particular packaging product has been placed on the market for the first time in the UK would need to be examined by reference to the particular circumstances of the case. Further guidance on this matter is available from the Local Authorities Co-ordinating Office on Regulatory Services (LACORS) (see contact points).

The reuse of packaging, for the same purpose for which it was intended, is not considered to be a further placing on the market and therefore such reused packaging **already in circulation** is not covered by these Regulations. Reusable packaging must fulfil the Essential Requirements and other requirements in the Regulations on its first placing on the market. Where packaging has been reconditioned, remanufactured, repainted or altered for a different use, for example, it will be considered “new” packaging and would need to meet the requirements of the Regulations when placed on the market.

The Regulations do not apply:

- a) To packaging* used for a given product (that is, the packaging has been packed or filled) prior to 31 December 1994;
- b) To packaging* manufactured on or before 31 December 1994 and lawfully placed on the market on or before 31 December 1999;
- c) To packaging* manufactured, packed or filled for export without being placed on the market in the United Kingdom;

* In all cases, packaging refers to the individual product, rather than the packaging design.

These Regulations do not affect the application of existing quality or labelling requirements for packaging, including those regarding safety, the protection of health and hygiene of the packed products, existing transport requirements or the provisions of Council Directive 91/689/EEC on hazardous waste. In other words, existing legislation on these matters must be complied with.

Obligation

The obligation to ensure that these Regulations are complied with lies with the responsible person. This is usually the packer/ filler or importer of packed or filled packaging. Compliance with the Regulations must be ensured when the packaged goods are placed on the market. In circumstances where the packaged product is marked with a brand or trade mark or other distinctive mark, the person so identified would normally be considered the packer/filler. It follows that, for an own-label product where the brand owner is not the packer/filler, the obligation to demonstrate compliance would fall upon the brand owner rather than the packer/filler.

The responsible person is obliged to ensure that all packaging (covered by these Regulations) complies with the essential requirements and heavy metal limits, in addition to the other provisions of the Regulations.

Essential Requirements

The essential requirements are:

1. Requirements specific to the manufacturing and composition of packaging.

All packaging subject to these Regulations must satisfy the following requirements:

a) Packaging shall be so manufactured that the packaging volume and weight be limited to the minimum adequate amount to maintain the necessary level of safety, hygiene and acceptance for the packed product and for the consumer. This is not considered to indicate a preference between material types (e.g. glass versus plastics) or packaging systems (e.g. single trip versus reusable), although consideration of the overall environmental impact of the packaging system used would be encouraged.

b) Packaging shall be designed, produced and commercialised in such a way as to permit its ... recovery, including recycling, and to minimise its impact on the environment when packaging waste or residues from packaging waste management operations are disposed of (see 2 and 3 below).

c) Packaging shall be so manufactured that the presence of noxious and other hazardous substances and materials as constituents of the packaging material or of any of the packaging components is minimised with regard to their presence in emissions, ash or leachate when packaging or residues from management operations or packaging waste are incinerated or landfilled.

2. Requirements specific to reusable packaging

Reuse is considered to be reuse for the same purpose for which the packaging was originally conceived. Packaging reused without alteration according to this definition need not comply with the Regulations after first use. The following requirements must simultaneously be satisfied if packaging is declared as reusable:

a) The physical properties and characteristics of the packaging shall enable a number of trips or rotations in normally predictable conditions of use;

b) It must be possible to process the used packaging without contravening existing health and safety requirements for the workforce;

c) The requirements specific to recoverable packaging when the packaging is no longer reused and thus becomes waste must be met (see paragraph 3).

Reuse is not the same as reworking or reconditioning used packaging. Enforcement authorities may wish to see appropriate technical documentation to establish that reuse does not involve alterations which might impact upon compliance. (See section on Compliance)

3. Requirements specific to the recoverable nature of packaging

All packaging, including reusable packaging, must fulfil at least one of the following:

(a) Packaging recoverable through material recycling.

Packaging must be manufactured in such a way as to enable the recycling of a certain percentage by weight of the materials used into the manufacture of marketable products, in compliance with current standards in the Community. The establishment of this percentage may vary, depending on the type of material of which the packaging is composed. The revised standard on packaging reuse provides guidance on a "certain percentage". This is taken to mean that the packaging must make a positive contribution to the output of the material recycling process for which it is considered suitable. In other words, if packaging is considered suitable for a metal recycling process, it must be possible to extract metal from the packaging in the recycling process.

(b) Packaging recoverable through energy recovery.

Packaging waste processed for the purpose of energy recovery shall have a minimum inferior calorific value (also known as 'minimum net calorific value') to allow optimisation of energy recovery. In the absence of harmonised standards, this is taken to mean that the packaging will make a positive contribution to the energy recovered in a waste incinerator.

(c) Packaging recoverable through composting.

Packaging waste processed for the purpose of composting shall be of such a nature that it should not hinder the separate collection and the composting process or activity into which it is introduced.

(d) Biodegradable packaging.

Biodegradable packaging waste shall be of such a nature that it is capable of undergoing physical, chemical, thermal or biological decomposition such that most of the finished compost ultimately decomposes into carbon dioxide, biomass and water.

Heavy Metal limits

The heavy metal limits refer to the sum of concentration levels of cadmium, mercury, lead and hexavalent chromium. The content of the specified heavy metals in packaging or any of its components must not exceed the following limits:

- 600 ppm by weight on or after 30 June 1998
- 250 ppm by weight on or after 30 June 1999
- 100 ppm by weight on or after 30 June 2001

A packaging component is defined as any part of the packaging that can be separated by hand or by simple mechanical means. An example would be a bottle top. This does not include permanent coatings or pigments which would be regarded as a constituent of the packaging (or of the packaging component) and would thus be part of any calculation, but not required to meet the heavy metal limits independently. As an example, if a steel drum was coated in lead chromate based paint, it would only exceed the limit if the lead chromate was greater than the limit in relation to the mass of the drum and the paint taken together.

Testing is not specifically required nor defined in the Regulations but note the section on 'Compliance' below. Compliance with the Heavy Metal limits is further addressed in Annex B.

The heavy metal limits do not apply to packaging which consists entirely of lead crystal glass.

There are two derogations from the heavy metals limits, which have been formally agreed at European level, and which have now been included in the Regulations. These cover the placing on the market of plastic pallets and crates and enamelled glass and glass that may have been contaminated with lead by old glass in the recycling process.

Derogation for plastic pallets and crates

Commission Decision 1999/177/EC established the conditions for a derogation for plastic crates and plastic pallets in relation to the heavy metals concentration limits in the Directive, and hence for the purposes of these Regulations. This derogation came into force in UK legislation on 25 August 2003.

Until 4 March 2009, the Derogation allows plastic pallets and crates with heavy metals concentrations greater than those permitted by the Regulations to be placed on the market if they fulfil a number of conditions, namely:

- The plastic pallet or crate concerned must have been manufactured in a controlled recycling process, involving a maximum of 20% virgin material, and for which the remaining feedstock was other plastic pallets and crates.

- None of the identified heavy metals are intentionally added during the production process
- The plastic pallet or crate may only exceed the heavy metal limits as a result of the addition of recycled materials

Further to this, the crates and pallets must be introduced in a controlled distribution and reuse system in which:

- New plastic pallets and crates containing the regulated metals are marked in a permanent and visible way
- A system of inventory and record-keeping is established
- The return rate of the pallets and crates over their lifetime is not less than 90%
- An annual declaration of conformity is drawn up by the responsible party, which must be made available on request for 4 years

Derogation for Glass Packaging

Commission Decision 2006/340/EC indefinitely extends the derogation in relation to the heavy metals concentration limits in glass packaging.

The derogation allows glass packaging heavy metals concentration limits greater than those permitted by the Regulations to be placed on the market if they fulfil a number of conditions, namely:

- No regulated metals have been intentionally introduced during the manufacturing process of glass packaging.
- The limits are exceeded only as a result of the addition of recycled materials containing heavy metals.
- That the responsible person placing the product on the market must submit a report to the enforcement authority verifying that the average heavy metals concentration levels of each glass furnace does not exceed a 200 ppm limit.

Compliance

The responsible person for the purposes of these Regulations should demonstrate compliance with the Regulations by providing the enforcement authorities on request with the necessary technical documentation. The responsible person must be able to supply technical documentation for a period of up to four years from the date on which the packaging is placed on the market. How and when such documentation is generated is not specified and is left to the person concerned; implicitly it could be compiled when a request is made by the enforcement authorities, although this would not be recommended as good practice. A request may be made at any time by the enforcement

authorities, but reasonable notice would normally be given to allow the documentation to be supplied. The documentation must be produced within a maximum of **28 days** of the enforcement authority making the request.

One approach which may help businesses to meet a request from enforcement authorities, would be if the responsible person had regard to the likely documentation required when designing new packaging. It will be the responsibility of the responsible person to ensure that information which shows that the packaging complies with the requirements, is presented. Illustrative compliance procedures in Annex A are offered for consideration, although they should not be regarded as definitive.

The use of the CEN standards will carry with it the presumption of conformity of the packaging with the essential requirements in all Member States. In other words, if the standards are used, the product will be considered to meet the essential requirements unless there are grounds for suspecting otherwise. These standards are available from British Standards Institute (BSI) see contact details on Page 18. It should be noted that the standards represent only one means of establishing conformity with the essential requirements, and that other means may be acceptable.

It may be appropriate for the responsible person to refer to their suppliers for relevant information, such as test results or technical information, or to specify requirements as part of the supply arrangements. However, it should be noted that such suppliers would normally only be able to provide information concerning those aspects of the essential requirements which are directly under their control and that legal responsibility remains with the responsible person. The umbrella standard (EN13427:2004) recommends the level in the supply chain at which the various assessments for conformity should be carried out.

Trade associations and materials organisations are encouraged to organise conformity testing or other supporting information covering their sectors to aid their members in assessing compliance. Where it is considered desirable to have an enforcement input into this, an approach can be made to LACORS.

Enforcement

It is the statutory duty of the following organisations to enforce the Regulations within their area:

- a) In England and Wales, weights and measures authorities (the trading standards departments of local authorities); and
- b) In Northern Ireland, the Department of Enterprise, Trade and Investment.
- c) In Scotland, weights and measures authorities (the trading standards departments of local authorities); prosecutions against infringement of the Regulations are brought by the Procurator Fiscal.

The enforcement authorities have available to them various powers based on the Consumer Protection Act 1987, including:

- Issuing suspension notices prohibiting the supply of packaging which is considered to breach the Regulations.
- Making test purchases
- Entering premises at any reasonable time
- Requesting compliance documentation, inspecting processes and performing tests

Enforcement practice will be based around the Home Authority Principle developed by LACORS. This means that any guidance given to a business by a 'home authority' (usually the one covering the area where the headquarters of the business is based) will be recognised by all Trading Standards Departments. The principle is designed to promote good practice and thereby protect the consumer and encourage fair trading, consistency and common sense. The four express aims of the Home Authority Principle are to:

- Encourage authorities to place special emphasis on goods and services originating within their area;
- Provide businesses with a home authority source of guidance and advice;
- Support efficient liaison between local authorities; and
- Provide a system for the resolution of problems and disputes.

Offences and Penalties

These Regulations introduce the following offences:

1. Contravening or failing to comply with the essential requirements and heavy metal limits, penalised by a fine up to level 5 on the standard scale (currently £5000) on summary conviction or an unlimited fine on conviction on indictment.
2. Failing to submit compliance documentation at the request of the enforcement authorities, penalised by a fine up to level 5 on the standard scale.

These Regulations refer to the following offences:

3. Contravening a suspension notice, penalised by up to 3 months imprisonment or a fine up to level 5.
4. Intentionally obstructing the enforcement authorities, penalised by a fine up to level 5.

5. Knowingly or recklessly making a false statement of compliance, penalised by a fine up to the statutory maximum on summary conviction (currently £5000) or an unlimited fine on conviction on indictment.

The defence of 'due diligence' applies to offences 1, 4 and 5. This means that a claim that a person took all reasonable steps and exercised all due diligence to avoid committing the offence may be made in defence. This may include reference to an act or default or information given by a third party, in which case it must be accompanied by information identifying the third party, or that information in possession of the person making the claim. In this case the provision in the Regulations of 'liability of persons other than the principal offender' allows the third party to be prosecuted as though they had committed the offence.

Where an offence by a corporate body is shown to have been committed with the consent, connivance or through neglect of any director, manager or similar officer of the corporate body, they shall be regarded as having committed the offence as well as the corporate body.

Contact points for further information

Enquiries should be addressed, in the first instance, to your local authority Trading Standards department (or ‘home authority’)

Contact details of your local Trading Standards Office can be found by entering your postcode at:

<http://www.tradingstandards.gov.uk/>

LACORS

(Local Authorities Co-ordinating Office of Regulatory Services)

LACORS

Local Government House

Smith Square

LONDON

SW1P 3HZ

Tel: 020 7665 3888

Fax: 020 7665 3887

<http://www.lacors.gov.uk/>

SEPA

(Scottish Environmental Protection Agency)

Erskine Court

The Castle Business Park

STIRLING

FK9 4TR

Tel: 01786 457700

Fax: 01786 446885

<http://www.sepa.org.uk/>

Environment Agency

Rio House, Waterside Drive

Aztec West, Almondsbury

BRISTOL

BS32 4UD

Tel: 08459 333111

<http://www.environment-agency.gov.uk/>

Northern Ireland Trading Standards Service

Department for Enterprise, Trade and Investment (DETI)

176 Newtownbreda Road

BELFAST

BT8 6QS

Tel: 0845 600 6262
Fax: 02890 253 953
Email: tss@detini.gov.uk
<http://www.detini.gov.uk/>

The Agencies' Interpretation of Packaging booklet is available from these addresses or your regional Environment Agency Office.

Enquiries regarding the Producer Responsibility Obligations (Packaging Waste) Regulations 1997 should also be referred to the Environment Agency (SEPA in Scotland, Environment and Heritage Service in N.I.).

Environmental Helpline

0800 585 794

The Helpline is a Government telephone enquiry service providing a comprehensive information and signposting service for firms seeking advice on a wide range of environmental issues that may affect their business. Case studies and guides to help with various packaging issues are available.

The Responsible Packaging Code of Practice, developed by INCPEN and endorsed by DTI, DEFRA and LACORS is available, priced at £5.00, from:

INCPEN (the Industry Council for Packaging and the Environment)

SoanePoint, 6-8 Market Place
READING
Berkshire RG1 2EG

Tel: 0118 925 5991
Fax: 0118 925 5993

<http://www.iflites.co.uk/resource/userdata/ipu/code20-03-03.pdf> (Free of charge)

These Guidance Notes are available free of charge online at:

www.dti.gov.uk/innovation/sustainability/index.html

The Packaging (Essential Requirements) Regulations 2003 S.I. No 1941 and the Packaging (Essential Requirements) (Amendment) Regulations 2004 S.I. No 1188 and the Packaging (Essential Requirements) (Amendment) Regulations 2006 (SI 2006 No 1492) are available from the DTI Recycling Policy Unit and online:

<http://www.opsi.gov.uk/si/si2003/20031941.htm>
<http://www.opsi.gov.uk/si/si2004/20041188.htm>
<http://www.opsi.gov.uk/si/si2006/20061492.htm>

A study looking at the compliance approaches of 22 companies with the Essential Requirement Regulations was commissioned by the DTI and is available free of charge online at:

www.dti.gov.uk/innovation/sustainability/index.html

Department of Trade and Industry

Sustainable Development and Regulation Unit
151 Buckingham Palace Road
LONDON
SW1W 9SS

Tel: 020 7215 5000
Fax: 020 7215 1340

www.dti.gov.uk/innovation/sustainability/packaging/page29072.html

Extracts from the draft British Standards are reproduced in the Annexes with the permission of BSI under licence number PD\1998 0971. They are included in this document **for guidance only**. The standards are available from:

British Standards Institution (BSI)

Customer Services
389 Chiswick High Road
LONDON
W4 4AL

Tel: 020 8996 9000
Fax: 020 8996 7001

cservices@bsi-global.com

<http://www.bsi.org.uk/>

The following Draft Standards are available from BSI and contain greater detail than presented in the Annexes:

Title	Current Standard Number
Packaging - Requirements for packaging recoverable by material recycling	EN 13430:2004
Packaging - Requirements for packaging recoverable through composting and biodegradation - Test scheme and evaluation criteria for the final acceptance of packaging	EN 13432:2000
Packaging - Requirements for packaging recoverable in the form of energy, including specification of minimum inferior calorific value	EN 13431:2004
Packaging - Requirements specific to manufacturing and composition - Prevention by source reduction	EN 13428:2004
Packaging – Reuse	EN 13429:2004
Packaging and the environment - Requirements for the use of European Standards in the field of packaging and packaging waste	EN 13427:2004
<p>Packaging - Requirements for measuring and verifying the four heavy metals and other dangerous substances present in packaging and their release into the environment –</p> <p>Part 1: Requirements for measuring and verifying the four heavy metals present in packaging.</p> <p>Part 2: Requirements for measuring and verifying dangerous substances present in packaging, and their release into the environment</p>	<p>CEN/CR 13695-1:2000</p> <p>CEN/CR 13695-2:2002</p>

Annex A

Illustrative Compliance Procedures

Design and Review processes

Wherever possible, it is recommended that the concerns represented by the essential requirements and heavy metals limits are addressed in existing packaging design and review processes, particularly where formal quality or environmental management systems are in use.

Existing Packaging lines

Although existing packaging portfolios may not refer to these concerns directly, other evidence of suitability for recovery processes may be found through primary evidence that such recovery does occur. In the case of other issues such as minimisation, supporting evidence as to the required strength of the packaging may be available through monitoring transit damage and similar parameters.

Overall

The following recommended procedures are written from the point of view of the design process. They can equally be applied to a review of an existing package.

In the procedures, packaging is considered as a packaging system made up of different functional units. Each functional unit may be a single packaging unit or made up of several packaging components, which in turn are made of packaging constituents or packaging materials. An example would be a packaging system for the transport of beverages. This could be a cardboard carton used to transport filled bottles. The cardboard carton and the filled bottles would be functional units, interacting within the system but separable without affecting the product. The bottle would be made up of components: the empty bottle, the bottle top and the label, for example. The packaging constituents would be the cardboard of the crate, the glass of the bottle, any inks or pigments used and the materials of the bottle top and the label.

The compliance procedure should be applied to a packaging system as follows:

1. The packaging system should be minimised by weight and volume to take account of the system chosen and interaction between functional units where, for instance, a thinner bottle may require a stronger carton.
2. All packaging components should comply with the heavy metal limits currently in force (see Annex B).
3. All packaging components should comply with the requirement that the presence of noxious and other hazardous substances be minimised as constituents of the packaging material with regard to their presence in ash, emissions or leachate.
4. Any reusable functional unit should comply with the reuse requirement, particularly if designing for reuse affects the criteria for minimisation by weight and volume.

5. Each functional unit should comply with at least one recovery process, although different functional packaging in a packaging system may comply with different recovery processes.

Minimisation

It should be noted that the choice of system and material does not fall within the compliance procedure. Once the system is chosen and materials specified, they should be the minimum required for the design criteria.

These design criteria should establish the minimum adequate volume and weight usable for the packaging without compromising its performance.

A list of the relevant performance criteria should be produced in order to identify which criterion (called the critical area) prevents a further reduction in the quantity of material used. If it is not possible to identify a criterion preventing further reduction, then there is scope for further reduction until one of the criteria becomes the critical area.

The performance criteria identified in the draft standard are:

Product protection

Examples include protection against vibration, compression, humidity, light, oxygen, microbiological contamination.

Packaging manufacturing process

Examples include container shape, thickness tolerances, size, tooling, specifications minimising production waste.

Packing/filling process

Examples include impact and stress resistance, mechanical strength, packing line speed and efficiency, stability, heat resistance, closing, minimum headspace, hygiene.

Logistics (including transport, warehousing and handling)

Examples include any handling requirement, space utilisation, palleting systems, damage resistance.

Product presentation and marketing Examples include product identity, brand recognition, labelling, retail display system requirements, pilfer resistance.

Consumer acceptance

Examples include unit size, ergonomics, tamper evidence, shelf life, dispensing methods, attractive presentation.

Information

Examples include product information, instructions, bar codes, expiry dates.

Safety

Examples include safe handling requirements, child resistance, hazard warnings, pressure release closures.

Legislation

Any requirements from national or international legislation or standardisation.

Other Issues

Other economic, social or environmental implication not considered above relevant to weight or volume of packaging.

Noxious and Hazardous Substances

Noxious and hazardous substances must be minimised with regard to their presence in emissions, ash or leachate when packaging or residues from management operations or packaging waste are incinerated or landfilled. This implies that any noxious or hazardous substances should be reduced to the minimum level required for the effective functioning of the packaging. Where the presence of noxious or hazardous substances is included by design, the same procedure as presented for minimisation can be applied. This should be done by applying the procedure to the material containing the noxious or hazardous substance, although allowance should be made for the possible substitution, in part or full, of the noxious or hazardous substance by an alternative.

If the presence of noxious or hazardous substances is due to impurities then it may be appropriate to regard this as a quality control issue rather than a functional criterion.

As the Regulations do not define noxious or hazardous substances, it is taken to mean any substance described as such in national or international law.

Reuse

Packaging must conform to the reuse requirement only when design criteria for other requirements, particularly minimisation, are developed with the intention of reuse. In other words, where packaging has been designed for reuse, and is therefore stronger and uses more material than single trip packaging, it must comply with the reuse requirement.

The requirements for reuse are fulfilled if:

- The physical properties of the packaging are such that it can be reused. That is, it must be capable of being unpacked and then repacked (with or without reconditioning).
- A reuse system is in place enabling the packaging to be reused. The recognised reuse systems are closed loop, open loop or hybrid systems. These are defined as follows:
 - A closed loop reuse system is one where reusable packaging is circulated by a company or an organised group of companies.
 - An open loop reuse system is one in which reusable packaging circulates amongst unspecified companies.
 - A hybrid system consists of a reusable packaging item which stays with the end user with no redistribution, and one way packaging used to transport the contents to the reusable packaging, (this must fulfil the essential requirements in its own right). An example of such a system would be detergent pouches used to refill a reusable container that stays in the home.

- Reusable packaging is subject to the same requirement of recoverability as set out below.

Recovery

Each recovery option (i.e. material recycling, energy recovery, composting and biodegradation) has its own requirements and design issues. Packaging must be designed to comply with at least one recovery option in full.

Material Recycling

To be considered to comply with this recovery process the packaging and its associated life cycle must be compatible with at least one specified recycling process. As such it depends on the criteria of the recycling process specified. The following is a general list of considerations common to recycling processes.

The considerations are:

- That raw materials in the combination used as packaging constituents should allow a positive contribution to the material reclaimed; that is, the packaging must contribute to the output of the recycling process;
- That effective emptying or residue removal is possible, to the extent that any remaining traces of product adhering to the packaging have no negative effect on the recycling process;
- That materials are separable if they may be required to undergo separate recycling processes (e.g. mixed plastics)
- That further aids or improvements to collection, sorting or recycling processes may be incorporated, (e.g. material identification markings, reduction in undesired materials).

Energy Recovery

Packaging composed of >50% by weight organic materials (e.g. wood, cardboard, paper and other organic fibres and plastics) shall be considered to comply. Thin gauge aluminium foil up to 50 µm thick shall be considered to comply.

If packaging does not fall into the above description, it may still comply by the application of the methods below:

1. Any packaging which has a calculated net calorific gain which is positive shall be considered to comply (described below).
2. Any packaging which has a positive net calorific gain determined experimentally, e.g. by ISO/DIS 1928 or ISO/5660: Part 1, shall be considered to comply.

The net calorific gain is defined as:

$$Q_{net} = Q - H_a$$

This must be positive for the packaging to be considered to comply.

Where:

Q is the energy released on combustion.

H_a is the energy required to adiabatically heat the post combustion residues of a material from ambient temperature to the final combustion temperature. In this case the ambient temperature is defined as 25°C and final temperature as 850°C.

Thus an example would be a composite with 66% cellulose, 23% lignin and 11% inert coating. Calorific gain = $(0.66 \times 8) + (0.23 \times 14) + (0.11 \times -1) = 8\text{MJ/kg}$

This calculation produces a positive value; the example would thus be considered to conform.

The table below may help:

Constituent	energy released from combustion, Q (MJ/kg)	energy required by combustion residue, H_a (MJ/kg)	calorific gain, $Q - H_a$ (MJ/kg) or Q_{net}
Paper Constituents			
- cellulose	16	8	8
- lignin	26	12	14
Plastics			
- polyethylene, PE	43	21	22
- polypropylene, PP	44	20	24
- polystyrene, PS	40	18	22
- polyvinyl chloride, PVC	17	8	9
- polyethylene terephthalate PET	22	10	12
Aluminium under 50 μm	31	6	25
Aluminium over 50 μm - inert	0	1	-1
Steel	0	0.4	-0.4
other inert material (ceramic, glass)	0	1	-1
Calcium Carbonate	-2	1	-3
Water (moisture)	-2	2	-4

Composting and Biodegradation

The conditions for composting and biodegradation are fulfilled when the packaging complies with the following:

- Packaging should be largely combustible solids; that is, the residue after incineration should be less than 50% of the packaging. This figure is taken as indicating the organic content.
- The organic materials should be inherently and ultimately biodegradable materials, that is break down to carbon dioxide, mineral salts, biomass and water or methane. Chemically unmodified materials of natural origin such as wood, wood fibre, paper pulp and jute are accepted as biodegradable for these requirements.
- The packaging should disintegrate in the waste treatment process.
- The packaging should not retard or adversely affect the waste treatment process.
- The packaging should not degrade the quality of the resulting compost.

Packaging material demonstrated to be organically recoverable in a particular form shall be accepted as organically recoverable in any other form having a smaller mass to surface ratio or wall thickness.

Annex B

Comments on Heavy Metals in Packaging

Although it is recognised that heavy metals are rarely intentionally added to packaging, there are some known uses that may occur. Companies should be aware of these applications and the possible need to undertake compliance checks.

- Glass (undecorated). Glass containers may contain lead due to its unintentional introduction to recycled glass. This may be from lead containing glass or old wine bottle capsules. Levels of lead over 600ppm have been detected in some European glass containers, and as there is no known environmental or health risk through heavy metals in glass, a derogation has been agreed at European level.
- Glass (decorated). Enamels used to decorated or print on glass may contain lead oxide as a basic component and cadmium may be used in bright red and yellow enamels. A number of major producers signed a voluntary agreement aiming to phase out the use of heavy metals in enamels in enamelled glass.
- Non-food grade plastics. Pigments containing cadmium are occasionally still found, as is the use of lead chromate for yellow, orange and red pigments. A derogation from the heavy metal limits has been agreed at European level for plastic pallets and crates manufactured by recycling old plastic pallets and crates in closed loop schemes. This derogation applies only until 4 March 2009.
- Drums. Lead chromate or other hexavalent chromium compounds may be used in some colours of coatings for metal drums.
- Non-food metal containers. Rarely, lead solder may be used in metal container construction.
- Pigments and inks. May in a few cases be based on lead, cadmium or hexavalent chromium compounds.

More generally, the specified heavy metals will occur in small levels in most materials and some level of compliance monitoring should be performed.

Compliance

It is recommended that, wherever possible, an upper limit of the heavy metal concentration is calculated on the basis of data from the constituent materials.

If testing is considered to be required, any suitable test for a given material or packaging may be used.

If such testing is carried out, particular care should be taken to ensure that a sample is representative of all the constituent materials and the proportion in which they are used. For

example, a sample taken from a drum could be seriously affected if the drum had a red stripe which contained lead chromate, yet the rest of the coating did not.

Some potentially useful standards and documents exist:

‘Survey of the content of heavy metals in packaging on the Danish market’
H. Andreasen, N. Bernth, I. Christensen, P.H. Jensen. (Danish DTI)

This document describes sampling and testing methods used in the survey, in particular the use of wavelength dispersive x-ray fluorescence (WDXRF) and microwave assisted acid digestion followed by inductively coupled plasma atomic emission and mass spectrometry (ICP - AES and ICP - MS).

United States Environment Protection Agency Methods:

US EPA Method 3050: Acid digestion of sediments, sludges and soils and other matrices. This method is used for the CONEG regulations, which are similar to the heavy metal limits in these Regulations, and uses ICP-AES, ICP-MS, graphite furnace atomic absorption spectroscopy (GFAA) and flame atomic absorption spectroscopy (FLAA).

US EPA Method 3052: Microwave assisted acid digestion of siliceous and organically based matrices. A total digestion method for glass similar to the Danish DTI method. It is a microwave assisted nitric and hydrofluoric acid digestion method.

US EPA Method 3060: This is an alkaline digestion method for extracting hexavalent chromium from soluble, absorbed and precipitated forms of chromium compounds in soils, sludges, sediments and similar waste. It is included as the other methods do not distinguish between trivalent and hexavalent chromium. This method can be followed by US EPA method 7196 or 7199 (colorimetrically by UV spectrophotometry or ion chromatography respectively).

Annex C

Indicative List

Illustrative examples for criterion (i)

Packaging

Sweet boxes
Film overwrap around a CD case

Non-packaging

Flower pots intended to stay with the plant throughout its life
Tool boxes
Tea bags
Wax layers around cheese
Sausage skins

Illustrative examples for criterion (ii)

Packaging, if designed and intended to be filled at the point of sale

Paper or plastic carrier bags
Disposable plates and cups
Cling film
Sandwich bags
Aluminium foil

Non-packaging

Stirrer
Disposable cutlery

Illustrative examples for criterion (iii)

Packaging

Labels hung directly on or attached to a product

Part of packaging

Mascara brush which forms part of the container closure
Sticky labels attached to another packaging item
Staples
Plastic sleeves
Device for measuring dosage which forms part of the container closure for detergents."

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